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09/502,498	02/11/2000	Andrzej Kilian	191106.407C2	5251

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EXAMINER

WALICKA, MALGORZATA A

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 01/21/2004

33

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/502,498

Applicant(s)

KILIAN ET AL.

Examiner

Malgorzata A. Walicka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Oct. 6, 2003 and Jan. 13, 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18-29, 31-37, 39-44, 46-64 and 67-70 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 6, 7, 9-15, 23-29, 31-37, 39-44 and 46-64 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 68 is/are allowed.
- 6) ☒ Claim(s) 16, 18, 69 and 70 is/are rejected.
- 7) ☒ Claim(s) 19 and 67 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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The Amendment filed on October 6, 2003, comprising amendments to the specification, claims drawings and sequence listing, as well as Supplementary Amendment to Sequence listing filed January 13, 2004 are acknowledged. Amendments have been entered as requested. Claims 5, 8, 17, 20-22, 30, 38, 45, 65, and 66 are cancelled. Claims 1-4, 6, 7, 9-15, 23-29, 31-37, 39-44 and 46-64 are withdrawn. Claims 16, 18, and 19 are currently amended. New claims 68-70 are entered. Claims 1-16, 18-29, 31-37, 39-44, 46-64, 67-70 are pending; claims 16, 18, 19, and 67-70 are the subject of this Office Action.

### **Detailed Office Action**

#### **1. Objections**

##### *1.1. Specification*

The amendment to the specification is acknowledged. The amendment is confusing, because the numbering of lines in pages is wrong.

The substitute specification is required including all the amendments to the specification, i.e., the preliminary amendment of Feb. 11, 2000, amendment filed May 13, 2002 and amendment filled Oct. 6, 2003. Please amend to Table 1 to the form it has in the allowed application 09/502,424. Please substitute the term "intron" or "exon" with "alternative intron/exon" when appropriate.

##### *1.2 Drawings*

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Amendments to the drawings are acknowledged. The titles of Fig. 11A and 11L are not correct; they should be changed to: "Truncated telomerase".

### **1.3 Claims**

Claim 19 is objected to as being dependent on claim 18 rejected under 35 USC, section 102(e). In addition, Please correct the language of claim 19. Before 90% insert "at least"; before "identity" insert "sequence".

In claim 70, to avoid confusion as to whether the recited polynucleotide sequence is spliced in or out, the examiner suggests using the term alternative intron/exon, in the same way as in the allowed claims and the specification of the parallel case 09/502,424.

## **2. Rejections**

### **2.1. 35 U.S.C. 112, second paragraph**

Claims 18, 65 and 66 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Rejection of claim 18 made in the previous Office Action is withdrawn, because the claim has been amended. Rejection of claims 65 and 66 is moot because the claims have been cancelled.

The new claim 70 is confusing, because the claim is directed to a protein comprising a splice variant of a reference human telomerase protein as presented in SEQ ID NO: 2 which is encoded by DNA molecule of SEQ ID NO: 1. SEQ ID NO: 2 is

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encoded by one of the splice variants of primary RNA transcript of the human telomerase gene. Please note that SEQ ID NO: 1 is not a genomic DNA of human telomerase.

*2.2. 35 U.S.C. 112, first paragraph*

Claim 16, and dependent claims 18-19, 22 and 65-66 were rejected in the previous Office Action under 35 U.S.C. 112, first paragraph, for lack of written description.

Rejection of claims 18 and 65-66 is moot, because the claims have been cancelled.

Rejection of claim 16 is maintained. The claim is directed to a large and variable genus of polypeptides for which the description of structure is insufficient in the claims and specification. The disclosure fails to sufficiently describe the genus of isolated proteins that are splice variants of any human telomerase gene. The representative species disclosed by the specification are limited to splice variants of human telomerase that are set forth in SEQ ID NO: 2 and those set forth by sequences enumerated in claim 18. SEQ ID NO: 2, encoded by SEQ ID NO: 1, is one of the splice variant of the primary transcript of genomic DNA encoding telomerase. Applicants' disclosure is insufficient to put someone skilled in the art in possession of the characteristic and features of other species of the genus of proteins consisting of a splice variant of any human telomerase gene. Neither the structure nor the function of all splice variants of human telomerase are sufficiently described in the specification. The specification

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provides the amino acid structure and function for many splice variants of a gene sequence capable of being spliced to encode a reference human telomerase of SEQ ID NO: 2. The sequences identifying these variants are enumerated in claims 18 and 65. The genus of splice variants of the human telomerase is a highly variable genus including proteins with telomerase activity, telomerase inhibitory activity, and other functions as well. As such, the disclosed species are insufficient to provide an identifying characteristic of all the members of the genus.

The examiner suggests cancellation of claim 16.

The new claim 69 is also rejected for lack of written description. The claim is directed to an isolated protein comprising a fragment of SEQ ID NO: 44, wherein the fragment comprises the following fragments of SEQ ID NO: 44:

- 1) 530-1096,
- 2) 824-1096,
- 3) 911-1096.

The claim is generic because it is directed to a large and versatile genus of proteins. Neither the structure nor the function of the genus are sufficiently disclosed by Applicants. The specification teaches one representative of the claimed genus that is splice variant of SEQ ID NO: 44. The structure of the variant is described, however its function is not sufficiently disclosed. Because this splice variant is a C-terminal truncated protein, it is assumed that some unknown regulatory function of C-terminal is lost.

While it is acknowledged that the current claim recites structural features that can be used to identify species within the claimed genus, as discussed in the written description guidelines the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by disclosure of relevant, identifying characteristics, i.e., structure and functional characteristics coupled with a known or disclosed correlation between function and structure, sufficient to show the applicant was in possession of the claimed genus. A representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The scope of claim 69 encompass any protein comprising said fragments, the rest of the structure of the claimed protein remains unknown, except for SEQ ID NO: 44. Satisfactory disclosure of a representative number depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus. In the instant case the claimed genus of claim 69 includes species, which are widely variant in function and structure. The description of structure of SEQ ID NO: 44 and suggestions as to its function are insufficient to be representative of the attributes and features of the entire genus.

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Thus, claim 69 contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Limiting the scope of the claim to proteins consisting of fragments of SEQ ID NO: 44 that are consisting of amino acid residues 530-1096, 824-1096, and 911-1096 will overcome this rejection.

### **2.3. 35 USC section 102**

Rejection of claim 16, 18, 19, 22, 65 and 66 under 35 U.S.C. 102(e) as being anticipated by Czech et al in the US Patent No. 6,166,178, is withdrawn because, as pointed out by Applicants in their traverse, the priority date of the patent does not anticipate the instant application.

Rejection of claims 22, 65 and 66 is moot, because the claims have been canceled.

Rejection of claim 19 over the sigma catalog is withdrawn, because the claim has been amended.

Amended claim 18 remains rejected under 35 U.S.C. 102(e) because the claim is directed to the protein comprising SEQ ID NO: 35. SEQ ID NO: 225 of the US Patent 6,093.809 comprises SEQ ID NO: 35, because SEQ ID NO: 35 consists of 588 of the N-terminal amino acid of SEQ ID NO: 225. Thus, the US Patent 6,093.809 anticipates claim 18.



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Cancellation of SEQ ID NO: 35 from claim 18 will overcome this rejection. As the splice variant of SEQ ID NO: 35 is novel, a new claim directed to the protein consisting of SEQ ID NO: 35 may be drawn.

**3. Allowable subject matter**

Claim 68 is allowed for the reasons indicated in the previous office Action.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

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Malgorzata A. Walicka, Ph.D.

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Patent Examiner

  
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